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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,448	02/11/2004	Winthrop D. Childers	200309247-1	4780

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EXAMINER

ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,448	CHILDERS, WINTHROP D.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 19, 21 and 32-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 19, 21 and 32-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

In response to the election/restriction requirement mailed on 10/11/06, the Applicant has amended claims to overcome the restriction requirement set forth between the method and apparatus claims. The sets of method and apparatus claims are now considered coexistent, therefore, the election/restriction requirement mails on 10/11/06 is hereby withdrawn. Therefore, all pending claims, 1-14,19,21, and 32-39 would be examined in this office action.

Allowable Subject Matter

The indicated allowability of claims 1-14,32-35,21,36, and 37 is withdrawn because after re-consideration, the indicated allowable subject matter is considered readable on the newly discovered reference(s) to 2005/0150489 A1. The Examiner apologizes for the inconvenience. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

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international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-14, and 32-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Tyvoll et al. US 2004/0163641 A1.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

As to claim 1, Tyvoll in figures 1-7 discloses a medicament dispenser comprising a fluid medicament supply (28/36), an ejector (24/114), an accumulator (40) in fluid communication with the ejector, a valve (26/126) in fluid communication with the fluid medicament supply and the accumulator, a sensor (18/88) configured to sense an accumulator characteristic, and a controller (12) configured to operate the valve in response to the accumulator characteristic.

As to claim 2, Tyvoll discloses where the sensor is configured to sense fluid pressure with the accumulator (pages 3 and 4, paragraph 36).

As to claim 3, Tyvoll discloses where the sensor is configured to sense volume defined by the accumulator (pages 3 and 4, paragraph 36).

As to claim 4, Tyvoll discloses wherein the sensor is fluidically coupled to the accumulator (see fig.1).

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As to claim 5, Tyvoll teaches where the sensor is configured to sense pressure adjacent the ejector (pages 3 and 4, paragraphs 36 and 39, and page 5, paragraphs 51,52,55, and 56).

As to claim 6, Tyvoll discloses a compliant member (page 4, paragraph 36, and page 5, paragraph 53) that regulates pressure within the accumulator

As to claim 7, Tyvoll teaches wherein the compliant member is configured to regulate pressure by deforming elastically in response to changes in the accumulator (page 4, paragraphs 36 and 39, and page 5, paragraphs 51,52,55, and 56).

As to claim 8, Tyvoll teaches wherein the compliant member is configured to regulate negative accumulator pressure (page 5, paragraph 54).

As to claim 9, Tyvoll teaches wherein the sensor is coupled to the compliant member to sense the accumulator volume (page 4, paragraphs 36 and 39, and page 5, paragraphs 51,52,55, and 56).

As to claims 10 and 11, Tyvoll lacks wherein the valve includes a micro valve, and wherein the micro valve includes an electrostatic actuator, magnetic actuator, or a piezoelectric actuator. However, the Applicant has not established why a particular type of valve is critical to the invention in terms of providing a specific function and solving a stated problem. Furthermore, one of ordinary skill in the art would consider Applicant's invention to perform equally well with the valve taught by Tyvoll because the ability of the valve to control fluid movement would not be affected by the type of valve. Therefore, it would have been an obvious matter of design choice to modify Tyvoll to obtain the invention as specified in claims 10 and 11.

As to claim 12, Tyvoll teaches a display (20/52) configured to provide information to a user of the dispenser.

As to claim 13, Tyvoll teaches wherein the information includes the number of does of medicament remaining the dispenser (page 2, paragraph 23).

As to claim 14, Tyvoll lacks wherein the information includes an indication to replace the fluid medicament supply, however, Tyvoll teaches a controlled ejection of a fluid-based solute medicament includes determining an indication of a characteristic of the medicament in at least one ejection chamber, and ejecting the medicament from the at least one ejection chamber based on the determined indication (see page 1, paragraph 4). Therefore, it would have been obvious to one of ordinary skill in the art to use the sensor and controller of Tyvoll's device to provide an indication signal suggesting to replace the fluid medicament supply because Tyvoll's device is capable of determining an indication of a characteristic (i.e. supply being empty) of the medicament in at least one ejection chamber.

As to claim 32, Tyvoll in figure 1-7 discloses an inhaler comprising a fluid medicament supply means (28/36); an ejector means (24/114); an accumulator means (40) in fluid communication with the ejector means; a valve means (26/126) in fluid communication with the fluid medicament supply means and the accumulator means.

As to claim 33, Tyvoll teaches a sensing means (18/88) configured to sense a characteristic of the accumulator means and a controller means (12) configured to operate the valve means in response to the sense accumulator characteristic.

As to claim 34, Tyvoll teaches wherein the compliant member is a resilient member (page 4, paragraphs 36 and 39, and page 5, paragraphs 51,52,55, and 56).

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As to claim 35, Tyvoll teaches wherein the controller is configured to operate the valve to increase the pressure adjacent the ejector (pages 3 and 4, paragraphs 36 and 39, and page 5, paragraphs 51, 52, 55, and 56).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19, 21, and 36-39 rejected under 35 U.S.C. 103(a) as being unpatentable over Tyvoll et al. US 2004/0163641 A1.

As to claims 19, 21, and 36-39, Tyvoll lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps (see above rejection cited for claims 1-14, 34, and 35). Thus, the method steps as cited in claims 19, 21, and 36-39) would have been obvious result of using the dispenser of Tyvoll.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,6,32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/777,449. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The limitation of instant **claim 1** can be found in the copending application claims 1 and 2. The difference between the copending application claim 1 and the instant claim 1 is that the copending claims 1 lacks the limitation of a valve, an accumulator, and a sensor of the instant claim 1 (see lines 4-7 of the instant claim 1), however, the limitation of a valve, an accumulator, and a sensor are found in the copending application claim 2.

The limitation of instant **claim 2** can be found in the copending application claim 3.

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The limitation of instant **claim 6** can be found in the copending application claim 4.

The limitation of instant **claim 32** can be found in the copending application claims 1 and 2. The difference between the copending application claim 1 and the instant claim 32 is that the copending claims 1 lacks the limitation of a valve, an accumulator, and a sensor of the instant claim 32 (see lines 4-7 of the instant claim 1), however, the limitation of a valve, an accumulator, and a sensor are found in the copending application claim 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Information Disclosure Statement

Applicant is requested to submit a copy of each of the foreign document cited in the Information Disclosure Statement filed on 7/25/05.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dunfield et al (US 2005/0150489 A1) is cited to teach a dispensing medicament with flow control means.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Shumaya B. Ali 3/19/07
Examiner
Art Unit 3771


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3/19/07